# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

BRIDGET CROZIER,

Plaintiff,

Civil Action No. 12-0008 (JBS/KMW)

v.

JOHNSON & JOHNSON CONSUMER COMPANIES, INC.,

Defendant.

MARGUERITE MCNAMEE,

Plaintiff,

v.

JOHNSON & JOHNSON CONSUMER COMPANIES, INC.,

Defendant.

Civil Action
No. 12-0010 (JBS/KMW)

#### OPINION

#### APPEARANCES:

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#### SIMANDLE, Chief Judge:

#### I. INTRODUCTION

Plaintiffs Bridget Crozier and Marguerite McNamee have brought these putative class actions alleging that Defendant Johnson & Johnson Consumer Companies Inc. has violated the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1, et seq, as well as the implied warranties of merchantability under N.J.S.A. § 12A:2-314, and of fitness under N.J. Stat. Ann. § 12A:2-314, in connection with the sale of Neosporin NEO TO GO! first aid antiseptic/pain relieving spray.

This matter comes before the Court on Defendant's Motions to Dismiss [Civ. No. 12-0008, Docket Item 4; Civ. No. 12-0010, Docket Item 4]¹ Plaintiffs' New Jersey Consumer Fraud Act ("NJCFA") and breach-of-warranty claims. The Court finds that federal law preempts any claims relating to the spray's label. In terms of the spray's advertising, the Court finds that Plaintiffs

<sup>&</sup>lt;sup>1</sup>Because the motions and briefing are virtually identical on the two dockets, the Court will only reference docket items in Civ. No. 12-0008, unless otherwise noted.

failed to state plausible claims for relief. The Motion to Dismiss will be granted. The NJCFA claims will be dismissed without prejudice, and the breach-of-warranty claims will be dismissed with prejudice.

#### II. BACKGROUND

The procedural history of the two cases, the factual and legal allegations contained in Plaintiffs' Complaints, and the arguments in Defendant's Motions to Dismiss are now discussed.

# A. Procedural History

Plaintiffs Bridget Crozier and Marguerite McNamee both filed lawsuits against Johnson & Johnson Consumer Companies Inc.

("J&J")<sup>2</sup> in New Jersey Superior Court, Camden County Law Division. The Complaints in both cases were virtually identical. Defendant removed both cases to this Court. The Court has jurisdiction over these actions pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d), because they are putative class actions having at least minimal diversity of citizenship, an aggregate amount in controversy in excess of \$5,000,000, and 100 or more class members. The two cases were consolidated for pre-trial purposes. [Docket Item 16.] Defendant has filed identical Motions to Dismiss in both cases. This

<sup>&</sup>lt;sup>2</sup>The lawsuits were actually filed against Johnson & Johnson Pharmaceuticals, and many documents contain that name. But counsel signed a joint stipulation changing the Defendant's name to Johnson & Johnson Consumer Companies Inc. [Docket Item 15.]

Opinion addresses both motions.

# B. Factual Background

Plaintiff Bridget Crozier filed a lawsuit individually and on behalf of other similarly situated individuals in New Jersey who purchased Neosporin NEO TO GO! first aid antiseptic spray since the product was introduced "in or around 2008." [Docket Item 1, Ex. A.]; (Compl. ¶ 6). Plaintiff Marguerite McNamee filed an identical Complaint. [Civ. No. 12-0010, Docket Item 1, Ex. A.]

Defendant J&J produces over-the-counter medications, including Neosporin antibiotic ointments and NEO TO GO antiseptic spray. (Compl. ¶ 2.) Neosporin antibiotic ointment's intended use is "the prevention of infection and pain relief at the sites of scratches, cuts and other minor wounds." (Id. ¶ 29.) It contains three antibiotics as active ingredients. (Id. ¶ 30.) J&J also produces Maximum Strength Neosporin, which contains the same three antibiotics and also a pain reliever. (Id. ¶ 31.) Both Neosporin antibiotic ointment and Maximum Strength Neosporin are "sold in boxes that, in an attempt to capitalize on the product's established goodwill and reputation, prominently display the Neosporin Signature Gold Mark and Neosporin Trade Dress." (Id. ¶ 32.) J&J also makes Neosporin NEO TO GO! Single Use Packets, which are "single use packets which each contain a single dose of original Neosporin antibiotic ointment." (Id. ¶ 34.)

In addition to these antibiotic ointments, J&J produces

Neosporin NEO TO GO! spray, which is the subject of this action. The spray "uses Benzalkanium Chloride as the active First Aid Antispetic," and its label identifies this active antiseptic ingredient. (Compl. ¶ 43.) It is sold in 7.7 ml (0.26 oz) spray bottles and "is specifically designed to fit anywhere to give you infection protection anytime, anywhere." (Id. ¶ 35.)

The antiseptic spray does not contain antibiotics, but Plaintiffs allege that the spray "is manufactured, marketed, advertised, and distributed in a manner that intentionally, recklessly, and/or negligently confuses and misleads consumers, including Plaintiff[s], into believing that they have purchased a product that contains antibiotics." (Id. ¶ 36.) The spray is allegedly marketed and labeled with the same green and yellow color scheme, Signature Gold Mark, trade dress, and goodwill and reputation that are associated with Neosporin, Neosporin Maximum Strength, and NEO TO GO! Single Use Packets, all of which contain antibiotics. (Id. ¶ 37.)

The Neosporin family of products also includes nonantibiotic products, such as Lip Treatment, Athlete's Foot Cream,
Athlete's Foot Spray Powder, Athlete's Foot Spray Liquid, and
Jock Itch Cream. (Id. ¶ 39.) These non-antibiotic products are
not marketed with the "Neosporin Signature Gold Mark or the
Neosporin Trade Dress and therefore do not capitalize on the
goodwill and antibiotic reputation associated with each of them."

# (<u>Id.</u> ¶ 40.)

Plaintiffs also allege that the spray is "significantly and exponentially more expensive . . . for a much smaller volume" than other brand name topical antiseptic products. (Id. ¶ 42.)

The spray, which contains 7.7 milliliters, costs \$4.00 to \$7.00.
(Id. ¶ 42.) A 16-ounce bottle of a common antiseptic typically sells for less than one dollar. (Id. ¶ 42.) Plaintiffs state that "[t]he extraordinary and unreasonable price differential between the subject spray and common antiseptic products can only be explained by the fact that Johnson & Johnson has intentionally, recklessly, and/or negligently misled consumers into believing that the subject spray contains antibiotic ingredients." (Id. ¶ 44.) Plaintiffs allege that consumers believe that "they are paying a higher price for the extra infection prevention that is provided by an antibiotic, when in fact the spray contains no antibiotics whatsoever." (Id. ¶ 44.)

Plaintiffs allege two counts. Count I alleges that J&J has violated the New Jersey Consumer Fraud Act ("NJCFA"). Plaintiffs allege that Defendant's actions constitute "unconscionable commercial practices, misrepresentations, concealment, suppression, or omission of material facts with the intent that Plaintiff[s] and members of the proposed class would rely on such concealment, suppression, or omission." (Id. ¶ 47.) Plaintiffs allegedly suffered "a measurable and easily-calculable economic

loss between the value of an antiseptic and the cost of the subject spray." (Id.  $\P$  49.)

Count II alleges that J&J breached implied warranties of merchantability and fitness for a particular purpose. Plaintiffs relied on J&J's "representations about the character, quality, and/or recommended uses of NEO TO GO! spray," (Id. ¶ 54), and J&J's "misleading marketing and advertising" breached implied warranties, (Id. ¶ 55). Plaintiff also alleges that "[t]hese breaches of warranties were substantial factors in inducing Plaintiff[s] and other New Jersey residents to purchase NEO TO GO! spray, and falsely indicated that the spray would provide infection protection in a manner similar to Johnson & Johnson's product lines." (Id. ¶ 55.)

### C. Defendant's Motions to Dismiss

Defendant filed identical Motions to Dismiss pursuant to Fed. Rule Civ. P. 12(b)(6). [Docket Item 4.] Defendant argued that Plaintiffs' claims are preempted by federal law and that Plaintiffs did not state a claim for relief under New Jersey law.<sup>3</sup>

 $<sup>^3</sup>$ J&J also argued that the claims should be dismissed under the prior pending action doctrine because Plaintiffs had an identical action, <u>Pang v. Johnson & Johnson Pharmaceuticals</u>, No. L-3309-10, N.J. Super. Law Div., Camden Cnty., pending in state court. But J&J withdrew this argument in its Reply brief because the <u>Pang</u> action was dismissed with prejudice and is no longer pending. (Def. Reply Br., at 5 n.l.) The Court will not address this argument as it is moot.

J&J argued that the spray is labeled in accordance with federal regulations and that federal regulations regarding over-the-counter medications prohibit states from imposing different labeling requirements. J&J stated:

Plaintiff asserts that state law imposes additional or different requirements - either adding a disclaimer of antibiotic content to the federally mandated ingredient label, or removing Defendant's lawful trademark and trade dress. . . . Those different and additional requirements would be preempted. . . .

(Def. Mem. Law Supp. Mot. Dismiss, at 2.)

J&J also argued that Plaintiffs did not state a claim under the NJCFA because Plaintiffs failed to plead elements required under the NJCFA and failed to state with particularity the alleged circumstances constituting fraud. In addition, J&J argued that Plaintiffs do "not allege that Defendant made any affirmative statement, either on the product label or in any advertising, that Neo to Go! spray contains antibiotics." (Id. at 10.) J&J noted that "[e]ntirely absent from the Complaint are any allegations that Defendant ever actually stated that Neo To Go! spray contained antibiotics; any allegations that the product failed to provide infection protection; and any specific allegations all [sic] relating to Plaintiff's purchase." (Id. at 4.)

And finally, J&J argued that Plaintiffs' warranty arguments "are duplicative and defective" because Plaintiffs did not allege that the spray was "unfit for its ordinary purpose" or that the

Plaintiff had any "particular purpose," of which Defendant had reason to be aware, that was different from the spray's "ordinary purpose." (Def. Mem. Law Supp. Mot. Dismiss, at 26-27.) J&J argued that Plaintiffs' warranty claims were "a restatement" of the NJCFA claim. (Id. at 26.)

#### III. Standard and Scope of Review

The Court next addresses the standard and scope of its review. The Court outlines the standard of review for a motion to dismiss in federal district court and rejects Plaintiffs' argument that the New Jersey state court standard of review, N.J. Rule Civ. P. 4:6-2(e), should apply. In addition, the Court explains which materials it can consider at this procedural posture. Finally, the Court explains why it cannot deny Defendant's motion to dismiss simply because Plaintiffs have noted prior state and federal cases in which J&J was a party.

#### A. Standard of Review

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court concludes that plaintiff has failed to set forth fair notice of what the claim is and the grounds upon which it rests that make such a claim plausible on its face. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). A complaint will survive a motion to dismiss if

it contains sufficient factual matter to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009). Although a court must accept as true all factual allegations in a complaint, that tenet is "inapplicable to legal conclusions," and "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." Id. at 678.

Additionally, "if a complaint is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." <a href="Phillips v. County of Allegheny">Phillips v. County of Allegheny</a>, 515 F.3d 224, 236 (3d Cir. 2008).

Plaintiffs erroneously describe the standard of review on a motion to dismiss under Rule 12. They argue that "Defendant possesses an extraordinarily heavy burden for a Rule 12(b)(6) Motion to Dismiss," and that a court "may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations."

(Pl. Br. Opp'n. Def. Mot. Dismiss ("Pl. Opp'n"), at 15-16, Mar. 8, 2012.)

Plaintiffs seem unaware that pleading standards in federal court have changed in the past five years: Before the Supreme Court's decision in <u>Twombly</u>, the test as set out in <u>Conley v. Gibson</u>, 355 U.S. 41, 45-46 (1957), only permitted district courts to dismiss a complaint for failure to state a claim if "it

appear[ed] beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."

Id. The Supreme Court rejected the "no set of facts" standard in Iqbal and Twombly. Iqbal "provide[d] the final nail-in-the-coffin for the 'no set of facts' standard that applied to federal complaints before Twombly." Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009).

Plaintiffs also described the "generous and hospitable" pleading standard that applies under New Jersey Rule 4:6-2(e), the rule governing motions to dismiss in New Jersey state courts. (Pl. Opp'n at 16.) But Fed. Rule Civ. P. 12(b)(6), not N.J. Rule 4:6-2(e), applies here. The Federal Rules of Civil Procedure "govern the procedure in all civil actions and proceedings in the United States district courts." Fed. R. Civ. P. 1. In this Court, the standards under New Jersey Rule 4:6-2 are irrelevant.

Essentially, Plaintiffs' assertion that they are "confronted with an exceedingly light threshold in order for [their] case to proceed beyond a 12(b)(6) motion," (Pl. Opp'n at 16), is wrong.

Plaintiffs also assert that "[t]he question as to whether Defendant's advertising violates the New Jersey Consumer Fraud Act cannot be determined pursuant to a 4:6-2(e) Motion to Dismiss." (Pl. Opp'n at 19.) The Court is not deciding a Rule 4:6-2(e) motion to dismiss; it is deciding a Rule 12(b)(6) motion. This Court must apply federal pleading standards, which

do not prohibit assessing whether Plaintiffs' Complaints contain a plausible NJCFA claim for relief.

The Court is mindful, however, that these cases were originally pled in the Superior Court of New Jersey and removed to this Court by Defendant. In formulating their Complaints, Plaintiffs and their counsel may reasonably have anticipated that their pleading needed to meet only the standard of N.J. Rule 4:6-2(e), which is rooted in the pre-Twombly and Igbal jurisprudence. If a pleading in a removed case falls short of the 12(b)(6) standard, it is important for the Court to exercise its discretion in favor of permitting Plaintiffs to attempt an amended pleading; that the original Complaints did not meet the enhanced standard for stating the grounds giving rise to a claim that is plausible on its face does not mean that the Plaintiffs could not meet this standard in their first attempt in federal court to do so.

# B. Consideration of Documents Outside the Complaints

Both Plaintiffs and Defendant attached documents to their briefing. In this section, the Court analyzes these different materials and explains why it either cannot or will not consider them.

In their Opposition briefs, Plaintiffs argue that their claims should stand because they have evidence obtained in discovery in a state court proceeding. They state, "Discovery in

similar litigation involving NEO TO GO Spray has resulted in a significant record" that allegedly substantiates their claims.

(Pl. Opp'n at 10.) They provide a 3-page chart listing various evidentiary sources that purportedly support their claims and that "represent only a fraction of the evidence accumulated. . . ." (Pl. Opp'n at 13.) A sampling of these documents includes: J&J's March 31, 1953 patent trademark for Neosporin, a check-out station photograph, a Neosporin Brand Identity Chart, a summary of J&J's television marketing campaigns, deposition transcripts, and e-mail exchanges between J&J employees. Plaintiffs also describe a Consumer Reports article, arguing that the spray is "so disingenuously and deceptively marketed, it became the focus of a Consumer Reports article." (Pl. Opp'n at 1.)

The Court cannot and will not consider these materials. "As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." In re

Burlington Coat Factory Sec. Litiq., 114 F.3d 1410, 1426 (3d Cir. 1997). If these materials were integral to or referenced in the pleadings, the Court could potentially consider them because "a document integral to or explicitly relied upon in the complaint may be considered. . . ." Id. at 1426.

But these materials were not integral to or referenced in the pleadings. All of the materials purportedly support the veracity of Plaintiffs' allegations that J&J's use of the

Signature Gold Mark and trade dress was intended to deceive consumers into believing that the spray contained antibiotics. At the motion to dismiss stage, the Court must assess whether Plaintiffs' allegations, if taken as true, establish a plausible claim for relief. Materials that purportedly bolster their allegations are irrelevant because the Court must already accept all factual allegations as true. If the allegations do not establish plausible claims, the Court must dismiss the Complaint, regardless of how much evidentiary support Plaintiffs purportedly have for their allegations.

Plaintiffs also attached copies of photographs of Neosporin, Maximum Strength Neosporin, and NEO TO GO! Single Packets. (See Pl. Opp'n at 4 (describing attached photographs).) These materials could potentially be considered by the Court since the Complaints directly discuss the similarity between the markings on these products and the spray. But the Court need not determine here whether it can consider these images because, for the purposes of evaluating the Motion to Dismiss, the Court must simply accept as true Plaintiffs' allegation that the spray has the same trade dress, trademark, and coloring as the antibiotic products. The documentary support for this allegation is, at this stage, irrelevant.

In addition to listing materials, Plaintiffs also describe television advertisements that J&J has used to market the spray,

directing the Court to certain aspects of the commercials. (E.g. Pl. Opp'n at 9.) To the extent that Plaintiffs reference exhibits in their Opposition to establish facts beyond those pled in the Complaint, the Court must disregard them. Plaintiffs cannot add factual allegations in Opposition; the mechanism for curing pleading deficiencies is to file an amended complaint pursuant to Fed.R.Civ.P. 15(a). "It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." Com. of Pa. ex rel. Zimmerman v. PepsiCo, Inc., 836 F.2d 173, 181 (3d Cir. 1988). The Court has not considered Plaintiffs' references to television commercials, and it has not watched the commercials that Plaintiffs submitted as exhibits with the Opposition briefs. At this procedural posture, the Court is simply assessing whether Plaintiffs have alleged plausible claims for relief.

In the Motion to Dismiss, Defendant attached copies of the NEO TO GO spray label. The Court finds that it need not determine whether the label is integral to or relied upon in the pleadings, and thus whether the Court could consider it, because Plaintiffs acknowledged all the facts that Defendant introduced the label to prove. Defendant introduced the label to show that the label identifies the product as an antiseptic and contains no claim that the product contains antibiotics. (Def. Mem. Law Supp. Mot. Dismiss, at 10-11.) But Plaintiffs acknowledged that the spray

label notes that the spray "uses Benzalkanium Chloride as the active First Aid Antispetic," (Compl. ¶ 43), and did not allege that the label claims any antibiotic ingredients. The Court will therefore assess the Motion to Dismiss without further considering the label because Plaintiffs' Complaints acknowledged the facts that Defendants sought to prove by introducing the label.

# C. Prior Court Decisions Involving Defendant

In their Opposition, Plaintiffs argue that "Defendant has made <u>identical</u> arguments in a New Jersey state court action involving the same underlying facts and legal issues," and "these arguments were rejected by both the trial court and by the New Jersey Appellate Division." (Pl. Opp'n at 14.) Plaintiffs argue that this Court should follow suit and deny the Motion to Dismiss presently at issue. (<u>Id.</u> at 14-15.) The Court must apply established precedent to the facts and arguments before it. The Court cannot deny Defendant's Motion to Dismiss based on Plaintiffs' assertion, absent any citations or quotations explaining legal reasoning, that another court did so in similar circumstances.

In their Opposition briefs, Plaintiffs also extensively cite Johnson & Johnson v. Actavis Group hf, 06 CIV. 8209 (DLC), 2008
WL 228061 (S.D.N.Y. Jan. 25, 2008), a case from the Southern
District of New York in which Plaintiffs Johnson & Johnson and

Johnson & Johnson Consumer Companies sued the Actavis Group, a manufacturer of antibiotic ointments that are packaged and sold as store-brands. Plaintiffs in that action argued that Actavis was copying the Neosporin Signature Gold Mark in order to confuse customers purchasing store-brand antibiotic ointments. Plaintiffs Crozier and McNamee claim that the Southern District of New York evaluated "Johnson & Johnson's assertions that the Signature Gold Mark is distinct in the marketplace as identifying a product as (a) manufactured by Johnson & Johnson and, inter alia, (b) representing antibiotic product. . . ." (Pl. Opp'n at 5.)

The Southern District of New York opinion did not discuss the perception that the Signature Gold Mark represents antibiotics. The case was about potential customer confusion regarding which antibiotic ointments J&J had produced, as opposed to store-brand competitors; there was no discussion of whether the Signature Gold Mark implies the existence of antibiotics in products that do not contain them. The court analyzed whether Johnson and Johnson's Signature Gold Mark was entitled to brand protection because it had acquired secondary meaning, which is the ability to identify the source of the product, rather than the product itself. The court found that "[m]uch of the evidence on which J&J relies to establish secondary meaning in the Gold Mark could be used as well to show consumer recognition of the NEOSPORIN brand name, which is indisputably a strong mark in its

own right." <u>Id.</u> at \*2. The court denied summary judgment on the secondary meaning issue because "while J&J's evidence of secondary meaning is sufficient for a jury to conclude that the Gold Mark has acquired distinctiveness in the marketplace, it is insufficient to establish secondary meaning as a matter of law." Id. at \*2.

That case does not support Plaintiffs' argument that the Signature Gold Mark connotes the presence of antibiotics, and it certainly does not support Plaintiffs' argument that J&J used the Signature Gold Mark on the spray so that consumers would think the spray contained antibiotics. It has no bearing on the Court's analysis of the present motion.

# IV. Analysis of Plaintiffs' Claims

The Court will now proceed to its analysis of the merits of Plaintiffs' claims. Defendant argues that Plaintiffs' claims are preempted by federal laws that govern the labeling of over-the-counter medications. For reasons next discussed, the Court finds that only claims relating to the product label are preempted. In terms of the spray's advertising, Defendant's argument that Plaintiffs failed to state an NJCFA claim is meritorious because Plaintiffs failed to allege that they actually noticed Defendant's advertising and that it misled them. Plaintiffs' NJCFA claims will be dismissed without prejudice to cure the deficiencies noted herein. In addition, Plaintiffs' warranty

claims will be dismissed with prejudice because Plaintiffs have not alleged that the spray had any defects and their claims pertain to marketing and consumer confusion, not product defects.

# A. Federal Law Preempts Plaintiffs' Labeling Claims

Defendant claims that "Plaintiff[s'] claims rest on the proposition that compliance with federal regulations that govern the labeling of ingredients on Neo to Go! Spray was insufficient.

. . ." (Def. Mem. Law Supp. Mot. Dismiss, at 6.) And J&J further argues that, with 21 U.S.C. § 379r, "Congress unambiguously stated its intent to preempt any state law which purports to impose additional or different requirements relating to the labeling of active ingredients on OTC medications. . . ." (Id. at 6-7.) Defendant is correct the Congress has preempted state laws that regulate labeling over-the-counter medications, but this preemption does not extend to Plaintiffs' marketing claims.

Under the Supremacy Clause of the United States

Constitution, federal law is the supreme law of the land and any conflicts between federal and state laws must be resolved in favor of federal law. Essentially, "state law that conflicts with federal law is without effect." Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (citing U.S. Const. art. VI, cl. 2).

Federal preemption of state law, however, "will not lie unless it is the clear and manifest purpose of Congress." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993) (citation omitted).

Defendant contends that Plaintiffs' state-law claims impose state law requirements that are expressly preempted under § 379r of the Food, Drug, and Cosmetic Act ("FDCA"). Section 379r(a) provides that states may not establish "any requirement . . . (1) that relates to the regulation of a [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]. . . . " 21 U.S.C. § 379r(a). Congress has therefore mandated that states may not create requirements different from the FDCA's requirements.

Pursuant to the FDCA, the Food and Drug Administration ("FDA") promulgated rules, under 21 C.F.R. § 201, that regulate the labeling of over-the-counter medications. Each product label must contain, inter alia, "the established name of each active ingredient and the quantity of each active ingredient per dosage unit," 21 C.F.R. § 201.66(c)(2), and "the principal intended action(s) of the drug," 21 C.F.R. § 201.66(c)(3). The active ingredient must be listed first. 21 C.F.R. § 201.66(c) (mandating that label information must be provided "in the order listed" and placing "active ingredients" immediately after the "Drug Facts" heading).

The FDA promulgated these rules specifically to address potential problems arising from brand confusion. When creating the labeling rules, the FDA received public comments arguing that

"product line extensions (i.e., OTC drug products with the same brand name that contain different active ingredients) invite the need for more prominent placement of the active ingredients" because "most consumers are able to recognize brand names but are unable to identify the relevant active ingredients." Over-The-Counter Human Drugs; Labeling Requirements, 64 Fed. Reg. 13254-01 at 13260 (Mar. 17, 1999). These comments informed the final rule:

This final rule requires the listing of active ingredients as the very first information. . . This location will enable consumers to quickly and systematically compare ingredients within products for similar uses. In addition, because the respective purposes will be listed next to each active ingredient, consumers will know why the ingredient is in the product. . . [S]uch uniform and prominent placement will help to ensure proper product selection, especially for product line extensions.

Id. The Federal Register notice thus shows that the FDA clearly contemplated the confusion that can arise when consumers become familiar with a brand name and see multiple different products with the same brand name. The FDA's solution for this potential problem was to require clear, accurate, and prominent listing of active ingredients and intended uses on product labels. The Federal Register notice does not specifically discuss signature marks or trade dresses, but the Court infers that the FDA considered these items because they are indicators of brand names and the FDA clearly considered the impact of brand name recognition. Federal regulations therefore specify the required

content on over-the-counter medication labels and, with 21 U.S.C. § 379r, Congress preempted state law claims regarding such labels. Any of Plaintiffs' claims that pertain to the spray's label are preempted.

Plaintiffs argue that preemption is inapplicable. They cite Wyeth v. Levine, 555 U.S. 555 (2009), to argue that the United States Supreme Court "dealt with prescription strength drug labeling (potentially a far more critical issue from a consumer safety standpoint) and still rejected a drug manufacturer's claim of preemption." (Pl. Opp'n at 28.) Wyeth is inapposite. In Wyeth, the Supreme Court considered whether the FDA's approval of a product label for a prescription anti-nausea medication provided a complete defense, via preemption, to a claim that the drug's approved label contained an inadequate warning. The Supreme Court held that state tort claims for inadequate warning on prescription medications were not preempted because "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. . . . Congress has not enacted such a provision for prescription drugs." Id. at 574. Wyeth thus involved a prescription drug, not an over-the-counter medication, and the two types of medications are regulated separately. See 21 U.S.C. § 379r, et seq ("National Uniformity for Nonprescription Drugs"). The Wyeth court, indeed,

also noted that "Congress pre-empted certain state requirements concerning over-the-counter medications and cosmetics but expressly preserved product liability actions." <u>Id.</u> at 575 no.8. Plaintiffs have not presented a product liability action, and they cannot use <u>Wyeth</u> to argue that federal preemption does not apply because <u>Wyeth</u> did not involve over-the-counter medications, for which Congress has enacted an express preemption provision in 21 U.S.C. 379r(a)(2).

Plaintiffs also argue that they are "not complaining that the label is inaccurate or incomplete;" rather, their claims are "predicated on allegations that advertising and marketing of NEO TO GO! spray were misleading or fraudulent. . . . " (Pl. Opp'n at 26.) As explained supra, FDA regulations cover the entire label, including indications of a product's brand name, and thus preempt challenges to a label, even if the challenge is not based on inaccuracy or incompleteness. To the extent that Plaintiffs imply that they have not challenged the label at all, the Court notes that while their Complaints primarily focus on advertising and marketing, they do refer to the spray's label. (See e.g., Compl.  $\P$  9.a. ("fraud in [J&J's] labeling"); Compl.  $\P$  50 ("deceptive and improper use of the Neosporin Signature Gold Mark, the Neosporin Trade Dress . . . on the subject spray")). Congress has expressly indicated its intentions in 21 U.S.C. 379r, and the FDA specifically considered brand name confusion in drafting its

regulations; Plaintiffs' present claims pertaining to the spray's label are preempted.

But, even though Plaintiffs' labeling claims are preempted, Defendant has not established that federal law preempts Plaintiffs' marketing claims. J&J cites Carter v. Novartis Consumer Health, Inc., 582 F. Supp. 2d 1271 (C.D. Cal. 2008) to support its preemption argument. But, although Carter found that some of the plaintiffs' claims were preempted, it did not dismiss their advertising claims on that basis. In Carter, the plaintiffs argued that the defendants had falsely labeled, advertised, and marketed over-the-counter cough medicines as safe and effective for children because they only warned against use under age two. Prior to the lawsuit, an FDA Advisory Panel concluded that the medications should not be used in children under age six, but the FDA itself only adopted the Panel's recommendation for children under age two. The Carter plaintiffs argued that the defendants "knew or should have known that OTC cough and cold medicines do not work and are dangerous to children under the age of six." Carter at 1276. The Carter plaintiffs thus presented a direct challenge to the FDA-approved language regarding appropriate product warnings. The Carter court held that preemption applied to some of the plaintiffs' claims because "[t]he touchstone of preemption under § 379r is the effect that a finding of liability on a particular claim would have. . . As long as that claim

imposes a requirement that is at variance with FDA regulations, it is preempted." <a href="Id.">Id.</a> at 1283. The <a href="Carter">Carter</a> plaintiffs' claims were at variance with FDA regulations because the FDA had specifically adopted age two, not age six, as the appropriate warning age for the medications and had approved labeling and advertising containing that age limit. Id. at 1284. The Carter court thus held that "claims based upon FDA-approved statements in product labeling and advertising are preempted." Id. at 1286. But the <u>Carter</u> court did not discuss preemption in regards to the plaintiffs' consumer fraud claims; the court dismissed those claims under Fed. R. Civ. P. 9(b) because plaintiffs "provide[d] no details of the alleged fraud" and did "not provide any facts relating to their reliance on Defendants' alleged misrepresentations." Id. at 1289. In the present case, the Court will dismiss Plaintiffs' NJCFA claims for the same reason, as explained infra.

#### B. New Jersey Consumer Fraud Act Claim

The New Jersey Consumer Fraud Act is designed to address "sharp practices and dealings . . . whereby the consumer could be victimized by being lured into a purchase through fraudulent, deceptive or other similar kind of selling or advertising practices." Smajlaj v. Campbell Soup Co., 782 F. Supp. 2d 84, 97 (D.N.J. 2011) (quoting Daaleman v. Elizabethtown Gas Co., 77 N.J. 267, 271 (1978)). It provides:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise . . ., whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice[.]

N.J. Stat. Ann. § 56:8-2. Courts "have emphasized that like most remedial legislation, the Act should be construed liberally in favor of consumers." Cox v. Sears Roebuck & Co., 138 N.J. 2, 15, 647 A.2d 454, 461 (1994).

Because NJCFA claims "sound in fraud or misrepresentation,"
Rule 9(b) of the Federal Rules of Civil Procedure applies.

Smajlaj v. Campbell Soup Co., 782 F. Supp. 2d 84, 91 (D.N.J.

2011); see also F.D.I.C. v. Bathgate, 27 F. 3d 850 (3d Cir. 1994)

(affirming district court's application of Rule 9(b) to NJCFA

claim). Rule 9(b) requires such claims to be pled with

"particularity." Naporano Iron & Metal Co. v. Am. Crane Corp., 79

F. Supp. 2d 494, 510 (D.N.J. 2000). A plaintiff must allege the

"who, what, when, where, and how" of the claim. Lum v. Bank of

Am., 361 F.3d 217, 224 (3d Cir. 2004). A plaintiff "may satisfy

this requirement by pleading the 'date, place or time' of the

fraud, or through 'alternative means of injecting precision and

some measure of substantiation into their allegations of fraud.'"

Id. at 224 (quoting Seville Indus. Mach. Corp. v. Southmost Mach.

Corp., 742 F.2d 786, 791 (3d Cir. 1984)). In class action cases,
each "individually named plaintiff must satisfy Rule 9(b)
independently." Pacholec v. Home Depot USA, Inc., 2006 U.S. Dist.
LEXIS 68976, \*4-5 (D.N.J. Sept. 25, 2006).

To state a claim under the NJCFA, a plaintiff must allege: (1) unlawful conduct by the defendant; (2) an ascertainable loss; and (3) a causal relationship between the defendant's unlawful conduct and the plaintiff's ascertainable loss. Frederico v. Home <u>Depot</u>, 507 F.3d 188, 202 (3d Cir. 2007). Unlawful conduct falls into three general categories: affirmative acts, knowing omissions, and regulation violations. Frederico v. Home Depot, 507 F.3d 188, 202 (3d Cir. 2007). The only possible unlawful conduct here is either an affirmative act or a knowing omission on Defendants' part because Plaintiffs have not alleged "violations of specific regulations promulgated under the NJCFA," which are required to establish regulation violations. See Cox at 19. Regardless of the category, "[t]he capacity to mislead is the prime ingredient of all types of consumer fraud." Cox v. Sears Roebuck & Co., 138 N.J. 2, 17 (1994). With respect to the causation element, "courts have found allegations that a plaintiff would not have purchased a product had it been accurately labeled or that they purchased the product because of the misleading claim are sufficient to plead causation." Mason v. Coca-Cola Co., CIV.A. 09-0220-NLH, 2010 WL 2674445 (D.N.J. June

30, 2010).

Neither Complaint alleges that the Plaintiffs were in fact misled by J&J's use of the Signature Gold Mark and trade dress in the spray advertising. The Complaints contain no information about when Plaintiffs saw J&J's advertising, when or where they bought the spray, why they bought the spray, whether they bought the spray because they thought it contained antibiotics, or whether Plaintiffs even noticed the Signature Gold Mark and trade dress. In short, neither Complaint alleges with particularity the gravamen of Plaintiffs' claims, i.e., that Plaintiffs bought the spray specifically because its advertising contained the

Neosporin trade dress and signature gold mark, thus leading them to believe that the product contained antibiotics. Plaintiffs' failure to plead that they were misled is fatal, particularly given the specificity that Rule 9(b) requires for NJCFA claims.

Plaintiffs argued in their Complaints that "[t]he extraordinary and unreasonable price differential between the subject spray and common antiseptic products can only be explained by the fact that [J&J] has intentionally, recklessly, and/or negligently misled consumers into believing that the subject spray contains antibiotic ingredients." (Compl. ¶ 44.) But the Complaints also acknowledge that the spray is sold in spray bottles and "is specifically designed to fit anywhere to give you infection protection anytime, anywhere." (Id. ¶ 35.)

Plaintiffs' own statements discount their assertion that the price differential can "only" be explained by misleading advertising that implied that the spray contained antibiotics. The spray's convenience and portability can also explain the price differential. Absent any allegations about the circumstances under which Plaintiffs chose to buy the spray, including whether the Defendant's advertising led Plaintiffs to mistakenly believe that the spray contained antibiotics, the Court cannot find that Plaintiffs have stated a plausible claim for relief under the NJCFA.4

Plaintiffs' remaining arguments require only brief attention. First, they cite the New Jersey Administrative Code for the proposition that it is unlawful to obscure material facts in advertisements, arguing that

Plaintiff's Complaint is supported by N.J. Admin. Code 13:45A-9.2(a)(5), which states '[w]ithout limiting the application of N.J.S.A. 56:8-1 et seq., the following practices shall be unlawful with respect to all advertisements: The use of any type, size, location, lighting, illustration, graphic depiction, or color resulting in the obscuring of any material fact.

<sup>&</sup>lt;sup>4</sup>Because the Court finds that Plaintiffs' allegations are insufficient to survive Defendant's Motion to Dismiss, the Court need not determine whether Defendant's alleged conduct was, in fact, unlawful and, if so, whether it would constitute affirmative actions or knowing omissions. In addition, the Court need not determine whether Plaintiffs have sufficiently pled that they have suffered ascertainable losses caused by Defendant's conduct. The Court declines to make those determinations because the insufficiency of Plaintiffs' pleadings makes them moot.

(Pl. Opp'n at 23 (emphasis omitted)). This citation is irrelevant. Plaintiffs have not alleged that J&J obscured any material facts; they have alleged that the use of the Neosporin Signature Gold Mark and trade mark confused customers into believing that the spray contained antibiotics.

Plaintiffs also cited Chattin v. Cape May Greene, Inc., 243 N.J. Super 590 (N.J. App. Div. 1990), for the proposition that "when a manufacturer (such as Defendant) makes . . . misrepresentations, and said misrepresentations are intended to be conveyed to the product's ultimate retail purchaser, the manufacturer can be held liable for violating the [NJCFA]." (Pl. Opp'n at 23.) In Chattin, homeowners sued the developer, who built and sold their homes, because the homes had been advertised to have insulated windows but, while the windows were doublepaned, the window frames were not insulated. The developer argued that the window manufacturer should also be liable. The Chattin court held that, even though the NJCFA permits manufacturer liability, the trial court had properly refused to submit the question of the window manufacturer liability's to the jury: "The trial court correctly found that there was no evidence that any of the homeowners with consumer fraud claims had seen, read, or relied upon [the window manufacturer's] brochure." Chattin at 607. Chattin supports the Defendant's Motion to Dismiss. Absent any showing that Plaintiffs had "seen, read, or relied upon"

J&J's use of the Neosporin Signature Gold Mark and trade dress in advertising, the Court must find that Plaintiffs have not stated a plausible claim for relief.

Plaintiffs also cite <u>Lieberson v. Johnson & Johnson Consumer</u>

<u>Cos.</u>, 2011 U.S. Dist. LEXIS 107596 (D.N.J. Sept. 21, 2011), for
the proposition that "the only time that courts reject Consumer
Fraud Actions pursuant to a 12(b)(6) Motion is if the complainedof conduct is nothing more than mere 'puffery'. . . ." (Pl. Opp'n
at 21.) <u>Lieberson</u> does not stand for this proposition. The

<u>Lieberson</u> court outlines several requirements for NJCFA claims,
including, <u>inter alia</u>, stating a plausible claim for relief
pursuant to <u>Igbal</u> and <u>Twombly</u>, stating a claim with particularity
pursuant to Rule 9(b), and stating a claim that alleges unlawful
conduct, causation, and ascertainable loss pursuant to the NJCFA.
The <u>Lieberson</u> court noted that mere puffery is not actionable
under the NJCFA, but it did not state that a NJCFA claim can only
be dismissed if the challenged statements are puffery.

<u>Lieberson</u> actually supports J&J's argument that Plaintiffs failed to describe with particularity their spray purchases or the advertisements that allegedly induced them to purchase the spray. The <u>Lieberson</u> court stated, "Plaintiff has nowhere alleged whether or when the advertisements quoted in the Complaint appeared . . ., nor has she alleged whether or when she viewed these advertisements. . . Thus, the Court finds that these

allegations are patently insufficient to satisfy Rule 9(b)."

<u>Lieberson</u> at 19-20. Essentially, Plaintiffs cited a case that highlights the primary shortcoming of their Complaints, <u>i.e.</u> their failure to plead with particularity when and why they purchased the spray, whether they believed the spray contained antibiotics, and, if they were misled, the advertising that led them to believe the spray contained antibiotics.

And finally, Plaintiffs argue that Defendant acknowledged the validity of their NJCFA claims when it filed petitions for removal from state court. Specifically, Plaintiffs state, "[i]n that petition, Defendant clearly sets forth the claims being asserted by plaintiff . . . are pursuant to the [NJCFA]. . . . Accordingly, there can be no serious dispute that Plaintiff has properly pled a cause of action. . . ." (Pl. Opp'n at 24-25.) This statement is wrong. The removal petitions' description of the nature of Plaintiffs' claims does not establish that Plaintiffs' pleadings are sufficient to survive a motion to dismiss.

The Court will dismiss Plaintiffs' NJCFA claims without prejudice and with leave to seek to amend with respect to misleading advertising of the product.

## C. Breach of Implied Warranty of Merchantability

Plaintiffs allege that Defendant has violated the implied warranty of merchantability, pursuant to N.J. Stat. Ann. § 12A:2-

- 314, which provides that merchantable goods must
  - (a) pass without objection in the trade under the contract description; and
  - (b) in the case of fungible goods, are of fair average quality within the description; and
  - (c) are fit for the ordinary purposes for which such goods are used; and
  - (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
  - (e) are adequately contained, packaged, and labeled as the agreement may require; and
  - (f) conform to the promises or affirmations of fact made on the container or label if any.

N.J. Stat. Ann. § 12A:2-314. Plaintiffs also allege that J&J has violated the implied warranty of fitness for particular purpose, pursuant to N.J. Stat. Ann. § 12A:2-315, which provides that

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

N.J. Stat. Ann. § 12A:2-315. These two warranties "protect buyers from loss where the goods purchased are below commercial standards or are unfit for the buyer's purpose." Altronics of Bethlehem, Inc. v. Repco, Inc., 957 F.2d 1102, 1105 (3d Cir. 1992). To establish a breach of either warranty, Plaintiffs "must show that the equipment they purchased from defendant was defective." Id.

Plaintiffs have not alleged that the spray was defective or

that it failed to provide infection protection and pain relief, the purposes for which it is intended. In fact, Plaintiffs'

Complaints contain no allegations whatsoever about any injuries that Plaintiffs sustained and how their use of J&J's spray impacted their healing processes. Even assuming, arguendo, that the spray should have contained antibiotics, Plaintiffs have not alleged that the lack of antibiotics prevented them from recovering from injuries or caused infections to occur or to worsen. Plaintiffs allege that these warranty breaches "induced" them to purchase the spray. But establishing a breach of the implied warranties of merchantability and fitness for a particular purpose requires a showing regarding the product's functionality, not the advertisements that allegedly induced a customer to purchase it.

The Court will dismiss this Count because Plaintiffs have not shown that the spray was defective or that it operated improperly. The dismissal will be with prejudice because the Complaints contain no indication that Plaintiffs had any problems with the spray's functioning; their claims lie solely with allegedly misleading advertising.

#### V. CONCLUSION

Defendant's Motions to Dismiss will be granted. Any claims relating to the spray's label are preempted by federal law and

must be dismissed with prejudice. Plaintiffs' NJCFA claims will be dismissed without prejudice and with leave to amend with respect to misleading marketing. Plaintiffs' breach of warranty claims will be dismissed with prejudice. The accompanying Order will be entered.

September 28, 2012

Date

S/ Jerome B. Simandle

JEROME B. SIMANDLE Chief U.S. District Judge